

**K212059 Surgical Face Mask**Dec 17, 2021  
169 days to decisionK212059 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k212059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 1, 2021
Decision date	Dec 17, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhongshan Saifute Labor Protective Articles Co., Ltd.</b>
Location	Zhongshan, CN
Contact	Qionghua Ke
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212059/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026